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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,301

07/10/2003

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EXAMINER

CHAO, ELMER M

ART UNIT

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3737

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,301	<b>Applicant(s)</b> KIMCHY ET AL.	
	<b>Examiner</b> ELMER CHAO	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Acknowledgement is made of the amendment filed 6/21/2008.

### ***Response to Arguments***

2. Applicant's arguments filed 6/21/2008 with respect to claims 1-4 and 6-8 have been considered but are moot in view of the new ground(s) of rejection.
3. Regarding Applicants' arguments with respect to Hassan, Examiner asserts that Hassan does suggest the need for orienting the ingestible device (see page 306, first paragraph under the 'Performance' section). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan, Barrett ('014), Schentag ('607), and Glukhovsky ('348) to include circuitry capable of sensing the orientation of the ingestible device in order to improve detection of radiation by the pill when the source is angled behind the battery side of the detector (for motivation see page 306, first paragraph under the 'Performance' section).
4. Regarding Applicants' pre-emptive arguments with respect to the finality of this Office Action, Examiner asserts that Applicants' arguments with respect to claim 8 in the Remarks filed 10/31/2007 were addressed. Specifically, as pointed out in them Response to Arguments section of the Office Action filed 12/13/2007, a new ground of rejection was provided for claims 1-4 and 6-8. To summarize Applicants' arguments with respect to claim 8 in the Remarks filed 10/31/2007, Applicants first restated the requirement to meet the limitations of claim 1, and secondly made the assertion "Zhang does not teach an ingestible device". Examiner informs that the ingestible device is a

limitation also described in claim 1 of the instant application. If Applicants require further elaboration beyond this point, Examiner advises Applicants to request an interview, or to provide clear, non-spurious arguments in the next response to this Office Action. Examiner does concede to the minor informality of not reciting the Schentag reference in the prelude of the rejection of claim 8 in the previous Office Action. However, this minor informality does not warrant the withdrawing of the finality of this Office Action. There is plenty of evidence to help Applicants to understand that the Schentag reference should clearly be included in the prelude of the rejection, such as the mere dependency of claim 8 from claim 1.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-4, 6, and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassan in view of Barrett et al (U.S. 4,595,014) and Schentag (U.S. 5,279,607), and in further view of Glukhovsky (U.S. 6,584,348).

**Regarding claims 1, 2, and 6**, Hassan teaches “A Radiotelemetry Pill for the Measurement of Ionising Radiation using a Mercuric Iodide Detector” (title). Regarding claim 1, Hassan teaches that “the radiation pill consists of a mercuric iodide crystal, amplifier, transmitter, and a 1.35V battery” (last paragraph, pg. 303). Hassan teaches

of “the pill’s plastic encapsulation” (last paragraph, pg. 306). Regarding claim 2, Hassan teaches that the “radiopill can also serve as a general purpose telemetric  $\gamma$ -ray detector” (last paragraph, pg. 302). Hassan teaches that “The radiopill was also tested as a beta detector” (first paragraph, pg. 307).

Hassan substantially discloses all the limitations as discussed above. Hassan does not disclose an ingestible device with a plurality of nuclear-radiation detectors arranged on the external surface of the ingestible device. However, Barrett ('014) teaches a nuclear radiation probe that includes multiple radiation detectors (C3, L51-53). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan to create an ingestible device with a plurality of nuclear-radiation detectors. Such a modification would help increase the area imaged are by not requiring the device to rotate fully in order to image the surrounding area (C3, L62-67). Glukhovsky ('348) teaches a capsule with electrode probes protruding out from openings of the capsule (Figure 2A). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan in view of Barrett ('014) to include a plurality of nuclear radiation detectors arranged around the external surface of the ingestible device. Such a modification would improve the sensitivity of the probes by not enclosing them by an encapsulation that could potentially attenuate the detectable radiation.

Hassan, Barrett ('014), and Glukhovsky ('348) teach the limitations as discussed above but fail to explicitly teach the system comprising circuitry adapted to determine the location of the ingestible device and reconstruct the diagnostic image based on the

location. However, Schentag ('607) teach means necessary to perform the wireless tracking and signal transmission of telemetry capsules (col. 2, line 64 – col. 3, line 28; col. 8, line 66 - col. 9, line 38). Additionally, Barrett ('014) do teach a radiation imaging probe and a system capable of detecting the location of the probe and to reconstruct an image based on the location (abstract; col. 1, line 63 – col. 2, line 15). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan, Barrett ('014), and Glukhovsky ('348) to include circuitry capable of sensing location and reconstructing a diagnostic image based on said location in order to allow for the position and the strength of the source of a tumor to be determined in the presence of background radiation (for motivation see Barrett ('014) col. 2, lines 16-22).

Hassan, Barrett ('014), Glukhovsky ('348), and Schentag ('607) teach the limitations as discussed above but fail to explicitly teach the system comprising circuitry adapted to determine the orientation of the ingestible device. However, Hassan does suggest the need for orienting the ingestible device (see page 306, first paragraph under the 'Performance' section). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan, Barrett ('014), Schentag ('607), and Glukhovsky ('348) to include circuitry capable of sensing the orientation of the ingestible device in order to improve detection of radiation by the pill when the source is angled behind the battery side of the detector (for motivation see page 306, first paragraph under the 'Performance' section).

Regarding **claims 3 and 4**, Hassan teaches that “the sensitivity of the pill has been found for  $^{99}\text{Tc}^m$ ,  $^{131}\text{I}$  and  $^{32}\text{P}$ ” (abstract).

Regarding **claim 7**, Hassan does not teach the radiotelemetry pill with a collimator, nor does it even hint at the mercuric iodide crystal being collimated.

7. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassan in view of Barrett et al., further in view of Glukhovsky and Schentag, further in view of Zhang et al. (Society of Nuclear Medicine, June 2000). Hassan, Barrett et al., and Glukhovsky substantially disclose all the limitations as discussed above. They do not disclose an ingestible device arranged as a Compton camera. However, Zhang teaches a transrectal imaging probe based on Compton camera techniques (No. 68, second sentence). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the invention to include a Compton camera probe as evidenced by Zhang. Such a modification would allow the ingestible device to have high sensitivity and high resolution (No. 68, second sentence).

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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6/21/2008